UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

March 6, 2018

Subject: BAYOTHRIN TECHNICAL
EPA File Symbol: 432-RLII
DP Barcode: 444562
Action Code: R060
Submission #: 990378
E-Sub #: 13329
PC Code: 129140 (Transfluthrin: 99%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
March 6, 2018

Through: Anwar Y. Dunbar, Ph.D., Acting Tox Team Leader
CITAB
Registration Division (7505P)

Anwar Y. Dunbar

To: Timothy Ciarlo
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)

Registrant: BAYER ENVIRONMENTAL SCIENCE

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
129140 Transfluthrin	99.0%
Other Ingredients:	1.0%
TOTAL:	100.0%

ACTION REQUESTED: "Please review MRID 50430801 and determine if it is adequate to support dermal sensitization toxicity data requirements. In your initial review of the 6-pack acute tox data submitted to support new active ingredient registration of 432-RLII, you noted that the dermal sensitization study (MRID 49617854) could only be classified as supplementary and that additional data would be needed. MRID 50430801 was provided in response. I have included a copy of the "initial acute tox review (DP #435644) for your convenience…

BACKGROUND: In a CITAB review dated August 18, 2017 for 432-RLII it was stated that the dermal sensitization study in MRID 49617854 was classified as supplementary because the report did not include a positive control study conducted within 6 months of the study with NAK 4455. It was stated that the classification of the study could be upgraded with a positive control study conducted within six months of the report date. The registrant has now provided a positive control study (MRID 50430801).

COMMENTS AND RECOMMENDATIONS:

1. The dermal sensitization study in MRID 49617854, with the positive control study in MRID 50430801, has been upgraded to acceptable. This study, with its negative findings, now satisfies the dermal toxicity study requirement for the registration of 432-RLII.

2. The following is the acute toxicity profile for 432-RLII based on the previous review dated August 18, 2017 and with an upgrade in the classification of the dermal sensitization study:

Oral LD_{50} (rat)	Toxicity Category IV	MRID 49617850	Acceptable
Dermal LD_{50} (rat)	Toxicity Category IV	MRID 49617851	Acceptable
Inhalation LC_{50} (rat)	Toxicity Category III	MRID 49617852	Acceptable
Eye Irritation (rabbit)	Toxicity Category III	MRID 49617853	Acceptable
Dermal Irritation (rabbit)	Toxicity Category IV	MRID 49617853	Acceptable
Dermal sensitization (g. pig)	Negative	MRID 49617854	Acceptable*

*Upgraded to acceptable with information from the positive control study in MRID 50430801.

3. The precautionary and first aid labeling statements remain the same as those specified in the CITAB review for 432-RLII dated August 18, 2017.

4. All acute toxicity data requirements for the registration of 432-RLII have been satisfied.

Reviewer: Byron T. Backus, Ph.D.
Date: March 2, 2018
Risk Manager (EPA): 03

This is the Acute Toxicity Data Evaluation Record (DER) for the dermal sensitization study (MRID 49617854) submitted to support the registration of EPA File Symbol 432-RLII (Bayothrin Technical).

2. PC CODE: 129140 (Transfluthrin 99%)

3. CURRENT DATE: March 2, 2018

4. TEST MATERIAL: From p. 12 of MRID 49617850: NAK 4455 technical active ingredient; described as a dark brown solid/liquid (melting point: 50° C, pH 4.4 (2% in water). For the inhalation study (see p. 11 of MRID 49617852) batch number was 250 987 and purity was 97.5% (from p. 63 of MRID 49617852 purity was 94.5%). The dermal sensitization study used the same batch but reported (p. 12 of MRID 49617854) 95.0% purity. From p. 8 of MRID 49617817: "The test item has a melting point at atmospheric pressure of 32° C."

Study	MRID	Results	Tox Cat	Core Grade
Dermal sensitization: Buehler Test / guinea pig / Bayer AG Toxicology Department, Wuppertal 1, Germany / Report No. 17920; Study No. T6029915 / 14 April 1989 / OCSPP 870.2600; OECD 406	49617854	12 male guinea pigs were each dermally treated (6-hr exposures) on the left flank with 0.5 mL undiluted NAK 4455 technical three times, with 7-day intervals between exposures. From p. 16 of MRID 49617854: "After lengthy cooling the test compound had the form of a solid mass at room temperature. For administration the substance was melted at 50° C, and remained liquid even after short cooling." Two weeks after the third exposure the guinea pigs were challenged (on the left flank) with 0.5 mL undiluted NAK 4455; a control (previously unexposed) group of 12 guinea pigs was similarly treated. Sites were scored at 24, 48 and 72 hours after challenge. Results: All scores following challenge in both the previously exposed and control guinea pigs were zero. There was no indication that the test material is a sensitizer.	(Negative)	A
Dermal sensitization: Buehler Test / guinea pig / Bayer AG Toxicology / Wuppertal, Germany / Report No. 18132 / Study No. T 9030448 / 22 June 1989 / OCSPP 870.2600; OECD 406	50430801	MRID 50430801 (conducted Nov. 8 to Dec. 8, 1988) is a positive control study with 1-Chloro-2,4-nitrobenzene (DNCB) using the same Buehler protocol and the same strain (DHPW) of guinea pigs as the study in MRID 49617854 (conducted July 12 to Aug. 12, 1988). Twelve guinea pigs received 3 once-a-week induction treatments with 0.5 mL of 1% DNCB in propylene glycol. An additional (negative control) group was exposed to 0.5 mL propylene glycol alone.		

		The guinea pigs were challenged (2 weeks after the last induction treatment) with 0.5% and 0.25% DNCB solutions. 12/12 induced & 0/12 negative controls showed a positive response at challenge to 0.5%; 8/12 induced & 0/12 negative controls had a positive response at challenge to 0.25%. The requirement for an historical positive control study within 6 months of the study on the test material has been satisfied.		

n.d. = not determined; Core Grade Key: A =Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap